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 Document History

1. Purpose

Management performs, as a minimum, annual reviews to determine the fitness and effectiveness of the quality system in achieving the stated quality objectives. This procedure establishes the method by which management reviews are performed within the [Name].

2. Scope

This procedure applies to [Name] quality system.

3. Responsibilities

A. [Third Level Manager]:

- provides information for review,
- assists in investigation of action items, and as directed
- ensures implementation of any system change identified in their respective area.

B. [Second Level Manager]:

- provides requested information as needed,
- may assist in the review activities, and
- ensures action items and plans issued are investigated and identified system change completed in their respective area.

C. [First Level Manager]:

• conducts management review, assigns action items and plans and

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approves system changes; and

- designates personnel to assist in the management review activities.
- D. [Quality Management System Manager]
 - coordinates and collects the information for the management review,
 - assembles summary report and documents action items and plans,
 - monitors implementation of system changes approved as a result of action items and plans, and
 - maintains management review reports.

4. Background

None(FDA)

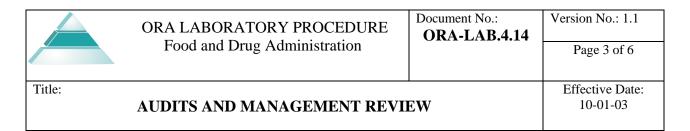
5. References

EAL-G3, Internal Audits and Management Review for Laboratories.

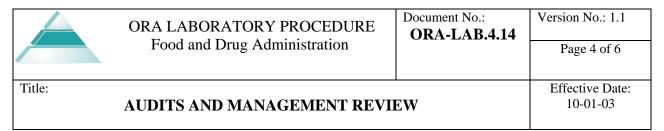
6. Procedure

A. Management review

- 1. As a minimum, an annual review of the quality system is performed. The predetermined schedule covering the elements of the International Organization for Standardization and the International Electrotechnical Commission (ISO/IEC) 17025 is found in Section 10 of Attachment A. This review examines the quality system and determines if it meets the conditions set by the agency and the standards. The review will serve as a guide in making future determinations towards the effectiveness and direction of the quality system. The quality system may need to be modified due to changes that have or are expected to take place in the organization, facilities, staffing, equipment, activities or workload.
- 2. The Quality Management System Manager assimilates the needed information and records for the review and forwards them to the [First Level Supervisor], [Second Level Supervisor], [Third Level Supervisor].
- 3. The review consists, but is not limited to the following:



- suitability of policies and procedures;
- reports from managerial and supervisory personnel;
- outcome of recent internal audits;
- effectiveness of previous actions taken;
- corrective and preventive actions;
- assessments by external bodies;
- results of interlaboratory comparisons or proficiency tests;
- changes in the volume and type of the work;
- client feedback;
- complaints; and
- other factors, such as quality control activities, resources and staff training.
- 4. The [First Level Supervisor, Second Line Supervisor] consolidates the findings and distributes the report to the [Second Line Supervisor, Third Line Supervisor] and [Quality Management System Manager]
- 5. If needed, a corrective action form is initiated for identified action items and plans by the QMS Manager for the assigned personnel to complete. Investigation is undertaken and findings submitted to the [First Level Manager, Second Level Manager] and [Quality Management System Manager].
- 6. Action items and plans are closed when the results of the investigation are implemented or are judged as having no added value to the quality system.



7. Definitions	Effectiveness – Effectiveness results when system requirements are routinely met.			
	Management review – Management review is the evaluation of the quality system by management to determine its effectiveness, suitability and future direction.			
	Requirement – A requirement is a declared, implied or routine need or expectation.			
	Suitability – Suitability is the property of a system with attributes that address the requirements for quality outlined in ISO/IEC 17025.			
8. Records	Management Review Report Action items and plans			
9. Supporting Documents	Volume II, Section 1, ORA-LAB.4.10 Corrective Action Procedure Volume II, Section 1, ORA-LAB.4.11 Preventive Action Procedure			
10. Attachments	Attachment A: Management Review Schedule Attachment B: Management Review			

Document History							
Version	Status	Date	Location of	Name & Title			
No.	(I, R, C)	Approved	Change History	Author	Approving Official		

Approving Official's signature:		Date:
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Document No.: ORA-LAB.4.14

Version No.: 1.1

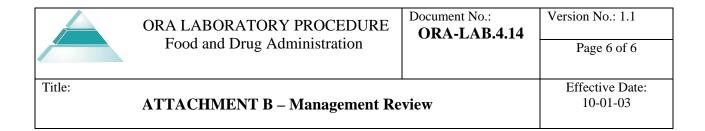
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Title:

ATTACHMENT A MANAGEMENT REVIEW SCHEDULE (EXAMPLE)

Effective Date: 10-01-03

Date of Management Review			
Quarter Performed: First	Second	Third	Fourth
Elements listed below are incl	uded in each ma	nagement revi	ew:
1. Quality System (4.2)			
2. Contract Review (Work	cplan and Chang	es in Work Loa	ad) (4.4)
3. Complaints (4.8)			
4. Corrective Actions (4.1)	0)		
5. Preventive Action (Acti	on Items/Plans)	(4.11)	
6. Audit Results (4.13)			
7. Effectiveness of Previo	ous Action Items	from Manager	ment Reviews (4.11, 4.14)
8. Training Program Sumr	mary (5.2)		
		Equipment	(5.5) Material (5.6)
10. Proficiency Testing Re	esults (5.9)		
Elements listed below are review.	included and are	e found in inter	nal audits for the management
1st Quarter: 4.1, 4.3		3rd Quarter	r: 4.9, 4.12
2nd Quarter: 4.6		4th Quarter	:: 5.4, 5.8, 5.10



DATE:

FROM: [Name]

TO: [Name]

SUBJECT: [Year] Management Review of Quality Management System

The annual management review was performed on [Date]. The purpose of this review of the quality management system is to monitor and evaluate the quality and fitness for use of services to agency needs. The review ensures the fitness and effectiveness of the quality management system.

Synopsis of findings includes: (a) policies and procedures, (b) managerial reports, (c) previous audits, (d) effectiveness of previous actions, (e) corrective actions and preventive actions (action items and plans), (f) outside assessments, (g) proficiency results, (h) changes in workload, (i) complaints, (j) resources, (k) training, and (l) other.

Conclusion

Recommendations

Provide a statement on the overall effectiveness of the [Name] quality management system.